

What is claimed is:

1. A method for extracting an analyte from a fluid sample, the method comprising the steps of:

- a) introducing the sample into a cartridge having:
 - i) a lysing chamber for lysing sample components to release the analyte therefrom, wherein the lysing chamber contains at least one filter for capturing the sample components by size exclusion as the sample flows through the lysing chamber;
 - ii) an analyte capture region containing capture material for capturing the analyte; and
 - iii) a reaction chamber;
- b) forcing the sample to flow through the lysing chamber to capture the sample components with the filter, wherein the volume of sample forced flow through the lysing chamber is greater than the volume capacity of the lysing chamber;
- c) lysing the sample components in the lysing chamber to produce a lysate containing the analyte;
- d) forcing the lysate to flow through the capture region, thereby capturing the analyte with the capture material;
- e) eluting the analyte from the capture region;
- f) forcing the eluted analyte to flow into the reaction chamber;
- g) reacting the analyte in the reaction chamber; and
- h) detecting a reaction product;

wherein the reaction requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and the method further comprises the steps of inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

2. The method of claim 1, wherein the analyte comprises nucleic acid, and wherein the steps of reacting the analyte and detecting the reaction product comprise amplifying the nucleic acid and detecting the amplified nucleic acid.

3. The method of claim 1, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted analyte with the reagents in the reagent chamber prior to forcing the analyte to flow into the reaction chamber.

4. The method of claim 1, wherein the step of lysing the sample components comprises transferring ultrasonic energy to the lysing chamber using an ultrasonic transducer coupled to a wall of the lysing chamber.

5. The method of claim 4, further comprising the step of placing a lysis buffer in the lysing chamber, the lysis buffer containing a lysing reagent.

6. The method of claim 4, wherein the transducer comprises an ultrasonic horn for contacting the wall.

7. The method of claim 4, wherein the step of lysing the sample components further comprises agitating particles or beads in the lysing chamber to rupture the sample components.

8. The method of claim 1, wherein the capture region comprises a channel or chamber containing the capture material, and the method further comprises the step of forcing a wash solution to flow through the capture region after the step of forcing the lysate to flow through the capture region and prior to eluting the analyte from the capture region.

9. The method of claim 1, wherein the capture region comprises a channel or chamber containing the capture material, and wherein the capture material comprises at least

one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.

10. The method of claim 1, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.

11. The method of claim 1, wherein the capture region comprises a channel or chamber containing the capture material, and wherein the analyte is eluted from the capture region by heating the channel or chamber containing the capture material while forcing elution fluid to flow through the channel or chamber.

12. The method of claim 1, wherein the cartridge has a first flow path that includes the lysing and capture regions, the first flow path leading to a waste chamber, the cartridge has an elution flow path passing through the capture region and diverging from the first flow path, the lysate is forced to flow through the capture region and into the waste chamber via the first flow path, and the elution fluid is forced to flow through the capture region and along the diverging elution flow path.

13. The method of claim 1, wherein the analyte is eluted from the capture region by forcing elution fluid to flow through the capture region, and wherein the volume of sample forced to flow through the lysing chamber is greater than the volume of elution fluid forced to flow through the capture region, whereby the analyte extracted from the sample is concentrated in the smaller volume of elution fluid.

14. The method of claim 1, wherein the ratio of the volume of sample forced to flow through the lysing chamber to the volume capacity of the lysing chamber is at least 2:1.

15. The method of claim 1, wherein the volume of sample forced to flow through the lysing chamber is at least 1 ml.

16. The method of claim 1, wherein the capture region comprises an extraction chamber containing the capture material, and wherein the volume of lysate forced to flow through the extraction chamber is greater than the volume capacity of the extraction chamber.

17. The method of claim 16, wherein the ratio of the volume of lysate forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1.

18. A method for extracting an analyte from a fluid sample, the method comprising the steps of:

- a) introducing the sample into a cartridge having:
 - i) a lysing chamber for lysing sample components to release the analyte therefrom, wherein the lysing chamber contains at least one filter for capturing the sample components by size exclusion as the sample flows through the lysing chamber; and
 - ii) an analyte capture region containing capture material for capturing the analyte;
- b) forcing the sample to flow through the lysing chamber to capture the sample components with the filter, wherein the volume of sample forced to flow through the lysing chamber is greater than the volume capacity of the lysing chamber;
- c) lysing the sample components in the lysing chamber to produce a lysate containing the analyte;
- d) forcing the lysate to flow through the capture region, thereby capturing the analyte with the capture material;
- e) eluting the analyte from the capture region;